MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLUmaximum strength non drowsy day and night cold and flu WAL-MART STORES INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Equate Maximum Strength Non Drowsy Day and Night Cold & Flu Do not take these products at the same time.

Drug Facts

Non Drowsy Day Cold & Flu

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

Uses

- · temporarily relieves these symptoms due to a cold or flu:
- \cdot minor aches and pains \cdot headache \cdot cough
- \cdot sore throat \cdot nasal and sinus congestion
- · temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- · more than 4,000 mg of acetaminophen in 24 hours
- · with other drugs containing acetaminophen
- · 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe

allergic reactions. Symptoms may include:

 \cdot skin reddening \cdot blisters \cdot rash \cdot hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than

2 days, is accompanied or followed by fever, headache, rash, nausea,

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

or vomiting, consult a doctor promptly.

- liver disease heart disease high blood pressure
- ◆ thyroid disease ◆ diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfa

When using this product do not exceed recommended dosage Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than7 days
- · fever gets worse or lasts more than 3 days
- · redness or swelling is present
- · new symptoms occur

· cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

· nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions

- · do not take more than the recommended dose
- · adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- · children under 12 years: do not use

Other information

Other information

store at room temperature. Avoid temperatures above 25°C (77°F).

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, potassium aluminum silicate, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

Questions or comments?

Questions or comments? 1-888-333-9792

Maximum Strength Night Cold & Flu

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

Uses

- · temporarily relieves these symptoms due to a cold or flu:
- · minor aches and pains · headache
- \cdot nasal and sinus congestion \cdot cough \cdot sore throat
- · runny nose · sneezing
- · temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- · more than 4,000 mg of acetaminophen in 24 hours
- · with other drugs containing acetaminophen
- · 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- · skin reddening · blisters · rash · hives
- · facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping

the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease heart disease high blood pressure
- ◆ thyroid disease ◆ diabetes ◆ glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than7 days
- · fever gets worse or lasts more than 3 days
- · redness or swelling is present
- · new symptoms occur
- · cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

 \cdot nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help

or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions

- · do not take more than the recommended dose
- · adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- · children under 12 years: do not use

Other information

Other information

• store at room temperature. Avoid temperatures above 25°C (77°F).

Inactive ingredients FD&C Blue #1, FD&C yellow #10, gelatin, glycerin, potassium aluminum silicate, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Questions or comments?1-888-287-1915

PRINCIPAL DISPLAY PANEL

EQUATE Maximum Strength Day & Night Cold & Flu

Compare to the active ingredients in

Alka-Seltzer PLUS® Maximum Strength Day

and Night Cold & Flu POWERMAX™ GELS

DAY NON DROWSY

Acetaminophen / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine HCI / Nasal Decongestant

Relieves:

Nasal Congestion

Headache & Body Ache Cough Sore Throat Sinus Pressure 12 SOFTGELS **NIGHT TIME** Acetaminophen / Pain Reliever-Fever Reducer Dextromethorphan HBr / Cough Suppressant Doxylamine Succinate / Antihistamine Phenylephrine HCI / Nasal Decongestant **Nasal Congestion** Headache & Body Ache Cough **Runny Nose** Sore Throat 4 SOFTGELS **16 SOFTGELS TOTAL**

*This product is not manufactured or distributed by Bayer

HealthCare LLC, owner of the registered trademark

Alka-Seltzer PLUS® POWERMAX™ GELS.



MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLU

maximum strength non drowsy day and night cold and flu kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49035-674

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49035-67	1 in 1 CARTON; Type 0: Not a Combination Product	11/16/2020	

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Quant	qualitity of Furts				
Part #	Package Quantity	Total Product Quantity			
Part 1	1 BLISTER PACK	12			

Part 1 of 2

MAXIMUM STRENGTH NON DROWSY DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration

ORAL

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg				
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg				
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg				

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ 989GH94E)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	

Product Characteristics					
Color	orange (Opaque)	Score	no score		
Shape	OVAL (oblong)	Size	16mm		
Flavor		Imprint Code	105		
Contains					

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

I	1	1 in 1 CARTON	
l	1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/16/2020		

Part 2 of 2

MAXIMUM STRENGTH NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg			
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg			
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients				
Ingredient Name	Strength			
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
SORBITOL (UNII: 506T60A25R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONE (UNII: FZ989GH94E)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
SORBITAN (UNII: 6092ICV9RU)				
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)				

Product Characteristics					
Color	green (opaque)	Score	no score		
Shape	OVAL (oblong)	Size	16mm		
Flavor		Imprint Code	106		
Contains					

Pa	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1		1 in 1 CARTON				
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	11/16/2020				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	11/16/2020			

Labeler - WAL-MART STORES INC (051957769)

Revised: 11/2021 WAL-MART STORES INC